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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,368	12/08/2000	Victor Rivera	394A US	1969

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10/01/2003

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

12

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,368

Applicant(s)

RIVERA ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

It is noted that claim 19 improperly depends from claims 1-18, and is treated as if it were written independent form. Claims 1-18 are directed to a method of "genetically engineering a primate." In light of the specification (para. bridging pages 6-7), genetically engineering the primate would require genetically engineering cells present in the primate at the time the transgene was introduced into the primate. This is not the case with the method of claim 19, where a primate cell is genetically engineered *ex vivo* and the cell is introduced into the primate. The cells present in the primate are not genetically engineered by the method, and thus the primate is not genetically engineered by the method.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with an adenovirus comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.
- II. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with an AAV comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.
- III. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with a retrovirus comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.

- IV. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with a hybrid adeno-AAV comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.
- V. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with herpesvirus comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.
- VI. Claims 14, drawn to a method for genetically engineering a primate for expression of a desired gene with lentivirus comprising the gene under control of an RSV promoter, classified in class 424, subclass 93.2.
- VII. Claim 19, drawn to a method of introducing a primate cell comprising a desired gene under control of an RSV promoter into a primate, classified in class 424, subclass 93.21.
- VIII. Claims 20-26, drawn to a method for genetically engineering a primate for regulating expression of a desired gene by introducing into the primate a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of an immunophilin, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 514, subclass 44.
- IX. Claims 20-25, drawn to a method for genetically engineering a primate for regulating expression of a desired gene by introducing into the primate a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of a

cyclophilin, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 514, subclass 44.

- X. Claims 20-25, drawn to a method for genetically engineering a primate for regulating expression of a desired gene by introducing into the primate a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of an FRB, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 514, subclass 44.
- XI. Claims 20-26, drawn to a method for genetically engineering a primate for regulating expression of a desired gene by introducing into the primate a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of an antibiotic resistance protein, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 514, subclass 44.
- XII. Claims 20-26, drawn to a method for genetically engineering a primate for regulating expression of a desired gene by introducing into the primate a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of a hormone receptor, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 514, subclass 44.
- XIII. Claims 27-33, drawn to a primate cell comprising a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion

protein comprises a ligand-binding domain of an immunophilin, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 435, subclass 363.

- XIV. Claims 27-32, drawn to a primate cell comprising a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of a cyclophilin, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 435, subclass 363.
- XV. Claims 27-32, drawn to a primate cell comprising a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of an FRB, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 435, subclass 363.
- XVI. Claims 27-33, drawn to a primate cell comprising a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of a antibiotic resistance protein FRB, and, in the presence of the ligand, regulates expression of the desired gene, classified in class 435, subclass 363.
- XVII. Claims 27-33, drawn to a primate cell comprising a transgene encoding a ligand-binding fusion protein under control of an RSV promoter, wherein the fusion protein comprises a ligand-binding domain of hormone receptor, and, in the

presence of the ligand, regulates expression of the desired gene, classified in class 435, subclass 363.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I-VI are unrelated to each other. While each of the methods are directed to the same goal, each makes use of a different recombinant virus. Each of the different recombinant viruses has a different mode of operation and different effects, and the different methods are not disclosed as being used together. Inventions VIII-XII are unrelated to each other. While each of the methods of inventions VIII-XII are directed to the same goal, each makes use of a transgene encoding a different fusion protein and a different ligand, the combination of which has a different mode of operation, and the different methods are not disclosed as being used together. Inventions XIII-XVII are unrelated, each of the cells comprises a transgene encoding a different fusion protein and a different ligand, the combination of which has a different mode of operation, and the different cells are not disclosed as being used together. Inventions I-VI are unrelated to inventions VIII-XII. These groups of methods have different modes of operation, different effects and different functions, and are not disclosed as being used together. Invention VII is unrelated to inventions I-VI or inventions VIII-XII. The method of invention V is not disclosed as being used together with the inventions I-VI or VIII-XII, and has a different mode of operation and produces materially different primates than inventions I-VI or VIII-XII.

Inventions VIII-XII and XIII-XVII, respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the primate cells of each of inventions XIII-XVII can be made by introducing the transgene into cultured primate cells.

Claims 1-18 link inventions I-VI. Claims 20-25 link inventions VIII-XII. Claim 26 links inventions VIII, XI, and XII. Claims 27-32 link inventions XIII-XVII. Claim 33 links inventions XIII, XVI and XVII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups, and have acquired a separate status in the art

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because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

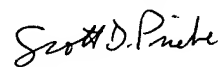
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Scott D. Priebe
Primary Examiner
Art Unit 1632